Amendments to the claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Original) A pharmaceutical composition comprising an electrospun fiber of a pharmaceutically acceptable polymeric carrier homogeneously integrated with a stable amorphous form of a pharmaceutically acceptable active agent.

2. (Original) The composition according to Claim 1 wherein the polymeric carrier is an amorphous polymer.

3. (Currently Amended) The composition according to Claim 1 ~~or 2~~ wherein the active agent is nanoparticle in size.

4. (Currently Amended) The composition according to Claim 1 ~~or 2~~ wherein the active agent is water soluble.

5. (Currently Amended) The composition according to Claim 1 ~~or 2~~ wherein the active agent is water insoluble.

6. (Original) The composition according to Claim 1 wherein the active agent is sparingly water soluble.

7. (Currently Amended) The composition according to Claim 1 ~~or 2~~ wherein the polymeric carrier is water soluble.

8. (Currently Amended) The composition according to Claim 1 ~~or 2~~ wherein the polymeric carrier is water insoluble.

9. (Currently Amended) The composition according to Claim 1 wherein the composition further comprises a surfactant which is a block copolymer of ethylene oxide and propylene oxide, lecithin, sodium dioctyl sulfosuccinate, sodium lauryl sulfate, ~~Tween~~ Polysorbate 20, 60 & 80, Sorbitan esters, Sorbitan Fatty Acids ~~Span™, Arlacel™~~, Triton X-200, polyethylene glycol, glyceryl monostearate, d-alpha-tocopheryl polyethylene glycol 1000 succinate, sucrose fatty acid esters ~~ester~~, ~~such as~~ sucrose stearate, sucrose oleate, sucrose palmitate, sucrose laurate, sucrose acetate butyrate, or mixtures thereof.

10. (Original) The composition according to Claim 9 wherein the surfactant is present in an amount of 0 to about 15% w/w.

11. (Currently Amended) The composition according to Claim 1 ~~or 9~~ wherein the composition further comprises an absorption enhancer.

12. (Original) The composition according to Claim 1 which provides a taste masking effect of the active agent.

13. (Currently Amended) The composition according to Claim 1 wherein the polymeric carrier is polyvinyl alcohol, polyvinyl acetate, polyvinyl pyrrolidone, hyaluronic acid, alginates, carragenen, cellulose derivatives such as carboxymethyl cellulose sodium, methyl cellulose, ethylcellulose, hydroxyethyl cellulose, hydroxypropylcellulose, hydroxypropylmethyl cellulose, hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, noncrystalline cellulose, starch and its derivatives such as hydroxyethyl starch, sodium starch glycolate, chitosan and its derivatives, albumen, gelatin, collagen, polyacrylates and its derivatives ~~such as the Eudragit family of polymers available from Rohm Pharma~~, poly(alpha-hydroxy acids), poly(alpha-aminoacids) and its copolymers, poly(orthoesters), polyphosphazenes, or poly(phosphoesters).

14. (Original) The composition according to Claim 13 wherein the polymeric carrier is polyvinyl pyrrolidone or polyvinylpyrrolidone-co-polyvinylacetate.

15. (Currently Amended) The composition according to Claim 13 wherein the polymeric carrier is Eudragit L100-55, Eudragit L30 D55, Eudragit L100, Eudragit S 100, Eudragit E 100, Eudragit EPO, Eudragit RL 30D, Eudragit RL PO, Eudragit RL 100, Eudragit RS 30D, Eudragit RS PO, Eudragit RS 100, Eudragit NE 30, or Eudragit NE 40, or a mixture thereof.

16. (Original) The composition according to Claim 1 wherein said drug substance is an analgesic, anti-inflammatory agent, anthelmintic, anti-arrhythmic agent, an antibiotic, anticoagulant, antidepressant, antidiabetic agent, antiepileptic, antihistamine, antihypertensive agent, antimuscarinic agent, antimycobacterial agent, antineoplastic agent, immunosuppressant, antithyroid agent, antiviral agent, anxiolytic sedative, astringent, beta-adrenoceptor blocking agent, contrast media, corticosteroid, cough suppressant, diuretic, dopaminergic, homeostatic, immunological agent, lipid regulating agent, muscle relaxant, parasympathomimetic, parathyroid, calcitonin,

prostaglandin, radio-pharmaceutical, sex hormone, steroid, anti-allergic agent, antihistaminic, stimulant, sympathomimetic, thyroid agent, vasodilator, PDE IV inhibitor, or a mixture thereof.

17. (Original) The composition according to Claim 1 wherein the drug substance is aspirin, (S)-3-Hydroxy-2-phenyl-N-(1-phenylpropyl)-4-quinolinecarboxamide; 6-Acetyl-3,4-dihydro-2,2-dimethyl-trans(+)-4-(4-fluorobenzoylamino)-2H-benzo[b]pyran-3-ol hemihydrate, Rosiglitazone, Carvedilol, Eposartan, hydrochlorthiazide, nifedipine, ketoprofen, indomethacin, (3R,3aS,6aR)-hexahydrofuro[2,3-b]furan-3-yl (1S,2R)-3-[(1,3-benzodioxol-5-ylsulfonyl)(isobutyl)amino]-2-hydroxy-1-{4-[(2-methyl-1,3-thiazol-4-yl)methoxy]benzyl}propylcarbamate, or a pharmaceutically acceptable salt thereof of any of these agents.

18. (Original) The composition according to Claim 1 in which active agent is present in an amount of about 1 to about 50% w/w.

19. (Original) The composition according to Claim 1 which is intended for oral administration.

20. (Original) The composition according to Claim 1 in which the active agent demonstrates improved bioavailability and/or improved stability, or has a modified or delayed absorption profile as compared to an immediate release dosage form.

21. (Original) The composition according to Claim 1 in which the electrospun fiber is encapsulated or compressed into a tablet or capsule.

22. (Original) The composition according to Claim 1 in which the electrospun fiber is further ground in size.

23. (Original) The composition according to Claim 1 which is results in a rapid dissolution of the fiber.

24. (Original) The composition according to Claim 1 which results in controlled release, sustained release, or pulsatile release of the active agent.

25. (Original) The composition according to Claim 1 which results in immediate release of the active agent.

26. (Original) Use of a composition according to Claim 1 for inhalation therapy.

27. (Original) Use of a composition according to Claim 1 for dispersion in an aqueous solution.

28. (Original) A process for making a stable formulation of an amphorous form of a pharmaceutically active agent comprising

a) making a solution of the active agent, and a pharmaceutically acceptable polymeric carrier with a pharmaceutically acceptable solvent; and

b) electrospinning the solution of step (a) into an electrospun fiber.

29. (Original) The process according to Claim 28 wherein the solvent is water miscible.

30. (Original) The process according to Claim 28 wherein the solvent is water immisicible.

31. (Original) The process according to Claim 28 wherein the solution is mixture of one or more solvents.

32. (Original) The process according to Claim 29 wherein the solvent is a mixture of water and a water miscible solvent.

33. (Original) The process according to Claim 28 wherein the solvent is ethanol, or a mixture of ethanol and methylene chloride or tetrahydrofuran.

34. (Currently Amended) The process according to Claim 28 wherein the polymeric carrier is polyvinyl alcohol, polyvinyl acetate, polyvinyl pyrrolidone, hyaluronic acid, alginates, carragenen, cellulose derivatives such as carboxymethyl cellulose sodium, methyl cellulose, ethylcellulose, hydroxyethyl cellulose, hydroxypropylcellulose, hydroxypropylmethyl cellulose, hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, noncrystalline cellulose, starch and its derivatives such as hydroxyethyl starch, sodium starch glycolate, chitosan and its derivatives, albumen, gelatin, collagen, polyacrylates and its derivatives ~~such as the Eudragit family of polymers available from Rohm Pharma~~, poly(alpha-hydroxy acids) and its copolymers such poly(caprolactone), poly(alpha-aminoacids) and its copolymers, poly(orthoesters), polyphosphazenes, or poly(phosphoesters).

35. (Original) The process according to Claim 34 wherein the polymeric carrier is polyvinyl pyrrolidone, or polyvinylpyrrolidone-co-polyvinylacetate.

36. (Currently Amended) The composition according to claim 34 wherein the polymeric carrier is Eudragit L100-55, Eudragit L30 D55, Eudragit L100, Eudragit S 100, Eudragit E 100, Eudragit EPO, Eudragit RL 30D, Eudragit RL PO, Eudragit RL 100, Eudragit RS 30D, Eudragit RS PO, Eudragit RS 100, Eudragit NE 30, or Eudragit NE 40, or a mixture thereof.

37. (Original) The process according to Claim 28 wherein the active agent is an analgesic, anti-inflammatory agent, anthelmintic, anti-arrhythmic agent, an antibiotic, anticoagulant, antidepressant, antidiabetic agent, antiepileptic, antihistamine, antihypertensive agent, antimuscarinic agent, antimycobacterial agent, antineoplastic agent, immunosuppressant, antithyroid agent, antiviral agent, anxiolytic sedative, astringent, beta-adrenoceptor blocking agent, contrast media, corticosteroid, cough suppressant, diuretic, dopaminergic, homeostatic, immunological agent, lipid regulating agent, muscle relaxant, parasympathomimetic, parathyroid, calcitonin, prostaglandin, radio-pharmaceutical, sex hormone, steroid, anti-allergic agent, antihistaminic, stimulant, sympathomimetic, thyroid agent, vasodilator, PDE IV inhibitor, or a mixture thereof.

38. (Original) The composition according to Claim 28 wherein the active agent is aspirin, (S)-3-Hydroxy-2-phenyl-N-(1-phenylpropyl)-4-quinolinecarboxamide, or 6-Acetyl-3,4-dihydro-2,2-dimethyl-trans(+)-4-(4-fluorobenzoylamino)-2H-benzo[b]pyran-3-ol hemihydrate, Rosiglitazone, Carvedilol, Eposartan, hydrochlorthiazide, nifedipine, ketoprofen, or indomethacin.

39. (Original) The product produced by the process according to Claim 28.

40. (Original) A process for making a stable formulation of an amphorous form of a pharmaceutically active agent comprising

a) melting the active agent and a pharmaceutically acceptable polymeric carrier to form a melt; and

b) electrospinning the melt of step (a) into an electrospun fiber.

41. (Currently Amended) The process according to Claim 40 wherein the polymeric carrier is polyvinyl alcohol, polyvinyl acetate, polyvinyl pyrrolidone, hyaluronic acid, alginates, carragenen, cellulose derivatives such as carboxymethyl cellulose sodium, methyl cellulose, ethylcellulose, hydroxyethyl cellulose,

hydroxypropylcellulose, hydroxypropylmethyl cellulose, hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, noncrystalline cellulose, starch and its derivatives such as hydroxyethyl starch, sodium starch glycolate, chitosan and its derivatives, albumen, gelatin, collagen, polyacrylates and its derivatives ~~such as the Eudragit family of polymers available from Rohm Pharma~~, poly(alpha-aminoacids) and its copolymers, poly(orthoesters), polyphosphazenes, or poly(phosphoesters).

42. (Original) The process according to Claim 41 wherein the polymeric carrier is polyvinyl pyrrolidone, or polyvinylpyrrolidone-co-polyvinylacetate.

43. (Currently Amended) The composition according to Claim 41 wherein the polymeric carrier is wherein the polymeric carrier is Eudragit L100-55, Eudragit L30 D55, Eudragit L100, Eudragit S 100, Eudragit E 100, Eudragit EPO, Eudragit RL 30D, Eudragit RL PO, Eudragit RL 100, Eudragit RS 30D, Eudragit RS PO, Eudragit RS 100, Eudragit NE 30, or Eudragit NE 40, or a mixture thereof.

44. (Original) The process according to Claim 41 wherein the active agent is an analgesic, anti-inflammatory agent, anthelmintic, anti-arrhythmic agent, an antibiotic, anticoagulant, antidepressant, antidiabetic agent, antiepileptic, antihistamine, antihypertensive agent, antimuscarinic agent, antimycobacterial agent, antineoplastic agent, immunosuppressant, antithyroid agent, antiviral agent, anxiolytic sedative, astringent, beta-adrenoceptor blocking agent, contrast media, corticosteroid, cough suppressant, diuretic, dopaminergic, homeostatic, immunological agent, lipid regulating agent, muscle relaxant, parasympathomimetic, parathyroid, calcitonin, prostaglandin, radio-pharmaceutical, sex hormone, steroid, anti-allergic agent, antihistaminic, stimulant, sympathomimetic, thyroid agent, vasodilator, PDE IV inhibitor, or a mixture thereof.

45. (Original) The composition according to Claim 41 wherein the active agent is, aspirin, (S)-3-Hydroxy-2-phenyl-N-(1-phenylpropyl)-4-quinolinecarboxamide, or 6-Acetyl-3,4-dihydro-2,2-dimethyl-trans(+)-4-(4-fluorobenzoylamino)-2H-benzo[b]pyran-3-ol hemihydrate, Rosiglitazone, Carvedilol, Eposartan, hydrochlorthiazide, nifedipine, ketoprofen or indomethacin.

46. (Original) The product produced by the process according to Claim 41.